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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/578,849	05/26/2000	Michael Z. Martin	031727.0001A	7983

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PRATS, FRANCISCO CHANDLER

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 08/13/2002 16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/578,849	MARTIN ET AL.	
	Examiner	Art Unit	
	Francisco C Prats	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 May 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-19 and 79-98* is/are pending in the application.

4a) Of the above claim(s) *94-98* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-19 and 79-93* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *15* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The amendment filed May 21, 2002, has been received and entered.

Claims 1-16 and 21-78 have been cancelled.

Claims 79-98 have been added.

Claims 17-19 and 79-98 are pending.

Election/Restrictions

Newly submitted claims 94-98 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

Claims 94-98 require that the extraction process must be performed under super- or near-critical conditions, but do not place any limitation on the chromatography step. Neither the originally filed claims nor the claims presently under examination recite such a process. Because the newly submitted claims recite a process having different steps than those originally presented and different than those under examination, restriction is clearly proper.

Since applicant has received an action on the merits for the originally presented inventions, these inventions have been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 94-98 are withdrawn from

consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 17-19 and 79-93 are examined on the merits.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 17, 18, 79, 80 and 88-92 are rejected under 35 U.S.C. 102(b) as being anticipated by Castor (U.S. Pat. 5,440,055).

Castor '055 discloses generally processes whereby taxol can be removed from extracts by chromatography in critical or near critical fluids. Castor '055 exemplifies a process whereby taxol is removed from an extract by chromatography in critical or near critical fluids including Freon-22, CO_2, methanol, methylene chloride, acetone, butanol and ethanol. Note specifically that methanol is used to elute a taxol-containing mass from the column. *See* Examples 5 and 6, at columns 17 and 18. A holding of anticipation over the cited claims is clearly required.

Claims 17, 18, 79, 80 and 88-92 are rejected under 35 U.S.C. 102(e) as being anticipated by Castor (U.S. Pat. 5,750,709).

Castor '709 discloses generally processes whereby therapeutic constituents present in natural sources can be purified by chromatography in supercritical, critical or near critical fluids. Castor '709 exemplifies a process whereby paclitaxol is removed from an extract by chromatography in critical fluids including Freon-22, CO_2, methanol, methylene chloride, acetone, butanol and ethanol. Note specifically that methanol is used to elute a taxol-containing mass from the

column. *See* Examples 5 and 6, at columns 19 and 20. A holding of anticipation is clearly required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 17-19 and 79-93 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lopez-Avila et al (J. High Resol. Chromatogr. 20:555-559 (1997)) and Schwabe (U.S. Pat. 5,296,224) in view of Castor (U.S. Pat. 5,440,055) and Castor (U.S. Pat. 5,750,709).

Each of Lopez-Avila and Schwabe disclose the preparation of extracts of kava root containing specific pharmacologically useful compounds, including kava lactones. *See* Lopez-Avila at abstract; *see* Schwabe '224 Examples 1-4, at cols. 3-7. Lopez-Avila and Schwabe differ from the claims in that neither reference uses supercritical, critical or near-critical chromatography as the separatory technique for extraction of the pharmacologically useful compounds.

However, both Castor '055 and '709 disclose that supercritical, critical or near-critical chromatography, using the claimed solvents including methanol, is a useful technique in recovering therapeutic compositions, such as taxols, from natural materials. *See, e.g.*, Castor '709 at abstract. Disclosed advantages of the technique include improved production capacity, improved scalability, greater overall efficiency, fewer processing steps, and improved product quality. *See* Castor '709 at col. 7, lines 23-37. Note specifically that Castor '709 discloses that the techniques disclosed therein are applicable generally to virtually any biomass which potentially contains therapeutic materials. *See* Castor '709 at col. 4, lines 35-38.

Thus, the artisan of ordinary skill at the time of applicant's invention, seeking to prepare therapeutic

compositions from kava root according to Lopez-Avila or Schwabe, would have been motivated by the Castor patents' disclosure of the advantages of supercritical, critical or near-critical chromatography to have employed supercritical, critical or near-critical chromatography to obtain therapeutic compositions and/or compounds from kava root. A holding of obviousness is therefore required.

It is noted that none of the cited references discloses the specific column media recited in claim 19. However, the claimed chromatographic column media were well known in the art at the time of applicant's invention. Thus, the artisan of ordinary skill would clearly have considered the determination of a suitable column media for chromatographic purification of a particular compound or compounds to be a matter of selecting from among known equivalents recognized in the art to be useful in the processes disclosed in the Castor patents. Similarly, the artisan of ordinary skill would have recognized that the determination of suitable temperatures and pressures for running Castor's columns, as recited in claims 81 and 82, would have been a routine matter of optimization on the part of the artisan of ordinary skill, and therefore necessarily *prima facie* obvious under § 103(a). Absent some evidence of an unexpected result inhering from the use of a particular chromatographic column

medium, or particular temperatures or pressures, the determination of suitable chromatographic conditions for application to Castor's techniques must therefore be held as obvious.

Response to Arguments

Applicant's arguments filed May 21, 2002, have been fully considered but they are not persuasive.

Regarding the anticipation rejections over the Castor patents, it is noted, as argued by applicant, that Castor's products are subjected to initial purification treatments. However, applicant's claims are sufficiently broad to encompass those treatments. The claims require the starting material to be "an extract . . . from a natural source" (claim 17) or "a plant extract" (claim 88). Contrary to applicant's arguments, it is clear that the material placed on Castor's columns has been extracted from a natural source. *See* Castor '055 at column 7, lines 16-33, disclosing the preparation of the extract from ground needles of the yew tree. The fact that the extraction comprises a series of purification steps does not make the extracted product any less "natural" or any less an "extract." Applicant's claims contain no language or limitation excluding the pre-treatments of Castor. In fact, by pointing to Castor's

initial extraction procedures, which include grinding and maceration, applicant bolsters the argument that Castor's starting material is an "extract" as that term is used in the claims. Moreover, while applicant urges that the term "extract" means at most that plant material has been prepared by optional grinding steps, pointing to page 19, line 12 of the specification, there is no definition of the term "extract" in this case which excludes an extract prepared by the pre-treatment steps disclosed by Castor. The anticipation rejections over Castor '055 and Castor '709 must therefore be maintained.

Regarding the obviousness rejection, contrary to applicant's argument, each of the Castor patents in fact explicitly discloses passing a plant extract over a column under supercritical conditions, as discussed at length above. Moreover, also contrary to applicant's argument, the comment in Schwabe's abstract about the water solubility of his kava extract must be taken in the context of Lopez-Avila's disclosure that therapeutic kava lactones are readily solubilized in the precise solvent system used by Castor to separate therapeutic compounds from plant extracts. Thus, taken as a whole the artisan of ordinary skill would have reasonably expected that applying Castor's techniques would have resulted in a suitable

method of preparing the therapeutic compounds from kava disclosed by Schwabe and Lopez-Avila. The rejection of record must therefore be maintained.

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Francisco C Prats whose telephone number is 703-308-3665. The examiner can normally be reached on Monday through Friday, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G Wityshyn can be reached on 703-308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Francisco C Prats
Primary Examiner
Art Unit 1651

FCP
August 9, 2002